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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,053	03/13/2003	Thomas Woods Keough	7379M	6283

27752 7590 08/18/2005

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,053

Applicant(s)

KEOUGH ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-7 drawn to a method of determining the amino acid sequence of a polypeptide comprising a specified polypeptide derivatization technique, mass spectrometric fragmentation analysis, and fragmentation pattern interpretation, classified in class 702, subclass 019. If this Group is elected, then the below summarized specie election is also required.

Group II: Claims 8-10 drawn to a kit for use in determining the amino acid sequence of a polypeptide comprising specified acidic moiety reagents, and a means for polypeptide derivatization, classified in class 702, subclass 019.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the subject matter of Group I is directed to a process of determining the amino acid sequence of polypeptides, whereas the subject matter of Group II is directed to a

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product that chemically cleaves polypeptides. The product can be used by materially different processes other than those disclosed by the applicant in Claims 1-7 (Group I), such as Edman degradation for sequence determination, chromatography, or electrophoresis for polypeptide detection. Thus, the search for both Groups together would present an undue search burden as they are directed to systems and/or methods that are generally distinct and separate in proteomics and polypeptide analysis.

SPECIE ELECTION REQUIREMENT FOR GROUP I

This application contains claims directed to patentably distinct species of the claimed invention. If Group I is elected, the applicant is further required to make one of the following specie elections for purposes of examination (i.e. select between Specie I-A or Specie I-B or Specie I-C).

Specie I-A: Method as set forth in Group I for determining the amino acid sequence of a polypeptide where the fragmentation analysis technique is MALDI PSD mass spectrometry.

Specie I-B: Method as set forth in Group I for determining the amino acid sequence of a polypeptide where the fragmentation analysis technique is electrospray ionization tandem mass spectrometry.

Specie I-C: Method as set forth in Group I determining the amino acid sequence of a polypeptide where fragmentation analysis is performed by any technique other than MALDI PSD or electrospray ionization tandem mass spectrometry.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claim 1** is generic to all of the above species. The species are distinct due to the distinct usage of mass spectrometric techniques as being directed to acquire a polypeptide fragmentation pattern. Claim 2 discloses two mass spectrometric techniques to provide a fragmentation pattern. MALDI PSD uses analytes mixed a large number of ultraviolet-absorbing matrix to ionize peptides. Electrospray ionization tandem mass spectrometry uses a liquid effluent containing peptides and a liquid chromatography column held at high electrical potential to ionize peptides (Nature, Sept. 2004, Vol. 5). However, there are a number of other distinct mass spectrometry techniques used for acquiring polypeptide fragmentation patterns (e.g. Fast Atom Bombardment mass spectrometry, Quadrupole 'Ion Trap' mass spectrometry, Affinity-Based Biomolecular mass spectrometry, Time of Flight mass spectrometry, http://www.genomicglossaries.com/content/mass_spectrometry.asp). Thus, the search for all species together would present an undue search burden as they are directed to separate methods for peptide ionization that are generally distinct and separate in proteomics and peptide sequencing.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 8/14/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER